K073053
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United Products and Instruments Inc.
"UNICO"

510(k) submission
Colpo-Master Colposcope

NOV 15 2007

510(k) Summary

(1) Submitter Information

Name: United Products and Instruments Inc. ("UNICO")

Address:

United Products and Instruments Inc.
182 E. Ridge Road
Dayton, NJ 08810

Telephone Number: 732-274-1155

Contact Person:

Dr. George Myers
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: June 21, 2007

(2) Name of Device

Trade Name: Colpo-Master
Common Name: Colposcope
Classification name: Colposcope

(3) Equivalent legally-marketed devices.

1. Wallach Zoom K853389
2. Intermed Zoom K031639
3. Welch-Allyn K955635

(4) Description

The Colposcope consists of three main assemblies: Microscope head and lens; Stand; and Illuminator. The microscope zoom head magnifies the area of the human body to be observed by a physician. It works like a "telescope" and the closest point is more than 300mm away from the body part. The microscope head and lens are made of optical glass, brass, steel, and aluminum.

(5) Intended Use

The UNICO Colposcope is intended for direct magnified viewing of the cervix, vagina, and external genitalia for the purpose of diagnosing abnormalities and selecting areas for biopsy.

(6) Performance Data

(a) Non-clinical tests

The Colpo-Master meets the requirements of IEC 601-1 and 601-1-2. The Colpo-Master has been tested to verify its specifications/

(b) Clinical tests

Clinical tests are not necessary, since the Colpo-Master uses the same technology as the predicate devices.

7) Conclusions

The Colpo-Master is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2007

United Products and Instruments Inc.
c/o Mr. Jason Launders
CITECH
5200 Butler Pike
PLYMOUTH MEETING PA 19462

Re: K073053
Trade/Device Name: UNICO Colpo-Master Colposope
Regulation Number: 21 CFR 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: October 29, 2007
Received: October 30, 2007

Dear Mr. Launders:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: UNICO Colpo-Master Colposcope

Indications for Use:

. The UNICO Colpo-Master Colposcope is indicated for direct magnified viewing of the cervix, vagina, and external genitalia for the purpose of diagnosing abnormalities and selecting areas for biopsy

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073053